Team Leader in Clinical Trials Supplies

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My team are responsible for coordinating the packaging & labelling of supplies for patients taking part in clinical trials of our investigational drugs.

What does your job entail on a day-to-day basis?

Managing a team of people (meetings with individual members of my group, coordinating their training & development and appraisals) as well as day-to-day document reviews, high level overviews of new clinical trials & assignment of these to staff, process improvements, updating standard operating procedures & anything else that comes my way!!

Since my role is very people-management & process improvement orientated at the moment, it might be better to give an overview of what someone in my team does day-today?  In which case here it is (in a very big nutshell):

My team need to coordinate all the activities required to produce clinical trial supplies.  The procedures involved in giving a patient an investigational drug — which is still undergoing testing and is not on the market for a specific disease — are quite complex. This is because the safety of the patient has to be a priority, and it is vital that the required data can be collected from the clinical trial.

The process starts when the people responsible for running the clinical trial send us a demand or ‘order’ to let us know that they want to run a clinical trial.  We will look at the clinical trial protocol and from this understand what the supplies need to physically look like (e.g. a vial of drug or placebo in a box), which depends on how & when the patient needs to take the drug (or placebo).  There might be a number of different configurations of drug and its associated packaging in one clinical trial.  E.g. at the first visit the patient might only need 1 vial/box, but on subsequent visits they might need 2 vials/box.  The amount of supplies that we need takes into account the number of patients in the study and its duration.  We also need to keep the expiry dates of the drug and the potential need to re-order new supplies of drug in mind at this point.

Once we know the nature of the clinical trial supplies that are needed, we can start to work on labels; the label is a term for printed information that accompanies the drug, and includes details such as how much and how often the patient should take the drug. Labels must comply to strict regulations (as per the ‘Orange Guide’ for the UK).  Clinical trials can be run anywhere in the world, so labels must adhere to local regulations/laws for each country and must be translated into the native language (which is sometimes more than one e.g. Belgium has 3!).  Once labels are designed & approved, they can be printed.  My team will print the physical labels, so need to know how to use the label design system & printers.  My team also prepare documentation for each batch of packed & labelled drug that has been manufactured for the packaging technicians (the team that stick labels onto our clinical trial supplies) – these can be quite complex instructions depending on the design of the packaging.  This documentation is approved by me and colleagues in quality assurance then released by a Qualified Person (that is, someone with the authority to say that the supplies can be used in the clinical trial). At this point, the supplies are deemed ‘fit for purpose’ for the clinical trial and can be shipped out around the world.

My team will make this happen! They will also keep oversight of those steps that are out of their immediate control (like quality assurance) in order to provide regular updates about timelines to colleagues who are running the clinical trial. Most of the time, my team members will be managing multiple jobs for different studies too. So organization skills are key!

There are other things that can impact my team. For example, there might be questions related to patient safety raised during the approval process for the clinical trial, which could mean that labels need to be amended or the patient’s visit schedule to the clinical trial site is changed (but generally this does not happen). In addition, some of our drugs are classed as controlled drug in certain countries, which adds another level of complication, as each country will have annual import quotas for controlled drugs that we have to be aware of.  Also, one of our products needs to be shipped under temperature-controlled conditions, which must monitored for the duration of the shipment to ensure that the drug is not affected in any way. There are many things to think about!

Since this is what my team do day-to-day, I also need to have an awareness of these processes & need to ensure the team are meeting their deadlines – i.e. the clinical trial sites have supplies so they can start the trial on time.

What qualifications are required?

No specific qualifications are required, but a background in life science would be advantageous, as would any project management qualifications.

We need to work to good manufacturing practice & have knowledge of good clinical practice and good distribution practice.  Clinical trials are governed by several guidelines, such as those from the International Conference on Harmonisation, the US Food and Drug Agency and the UK Medicines and Healthcare Products Regulatory Agency, so it is important to understand these guidelines for the job.

What other transferable skills do you need?

You need to be organized and have good time management, good communication skills, computer skills (Microsoft project/excel), presentation skills

Are there opportunities to widen your knowledge of other areas in your field?

Widening knowledge is mainly in terms of obtaining enhanced knowledge in the design and running of clinical trials, distribution of drugs (their import/export – especially of controlled drugs) and increasing our awareness of the roles of quality assurance and Qualified Person

Is training continual? Career Progression?

Yes – we always need to be aware of regulations, which may impact training for example awareness of new or revised standard operating procedures. There are also opportunities for enhancing the efficiency of processes that are used in clinical trial packaging and labeling. In addition, there are opportunities for online training such as ‘Pharma School’ (<http://www.pharmaschool.co/>) and other training courses as needs arise e.g. communication and negotiating skills etc.

What do you enjoy the most in your job?

Trouble shooting – fixing when things go wrong – it gives me a sense of achievement to know that I’ve got something back on track. And it may sound strange, but I enjoy working to deadlines as it makes it easier to prioritise my workload

Working in clinical trials gives me a great sense of satisfaction, as I know that the clinical trial supplies we prepare & ship will go directly to patients and (hopefully) have a positive impact on their lives. Our drugs are used for patients with a wide variety of conditions such as multiple sclerosis, cancer pain and epilepsy, which are extremely debilitating. The knowledge that our drugs can help to treat these conditions and make a real difference to the quality of people’s lives is a great reason to go to work every day!

What challenges do you have to overcome?

Managing timelines of different stakeholders in the clinical trial – for example balancing the needs and demands of the people who are running the clinical trial versus when we can physically get the required supplies to them.

Any advice for those interested in a position such as yours?

Most common knowledge gaps of people who want to move into this sort of role are in clinical trials knowledge & working in a good manufacturing practice environment (as well as knowledge of good clinical practice and good distribution practice). So it would be an advantage to have researched these areas.

What sources did you use to find out about the job vacancy?

Networking – through a friend who works at the same company.

Is there anything that you miss about being in the lab (if you were previously a lab-based scientist)?

Hands on work (I am desk-based), losing scientific lab-based skills e.g. HPLC